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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,602	12/12/2003	Hao-Jan Lin	JCLA10516	1741
23900	7590	10/18/2006	EXAMINER	
J C PATENTS, INC. 4 VENTURE, SUITE 250 IRVINE, CA 92618			GUIDRY, GUY L	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/735,602	Applicant(s) LIN ET AL.	
	Examiner Guy Guidry, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a response filed 23 August 2006 to the Office Action mailed 31 May 2006. Claims 1 and 11 have been amended. Claims 1-15 are currently pending in this application and under consideration in this Action. All previous objections/rejections not repeated herein are hereby withdrawn. A response to Applicant's arguments will be set forth, where appropriate, immediately following any statement of rejection repeated herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10-13 and 15 were rejected under 35 U.S.C. 102(b) as being anticipated by Bellhouse et al., 1994, WO 94/24263 (hereinafter Bellhouse).

Applicant argues that Bellhouse fails to disclose a sample delivery system comprising a pressured chamber provided with a pressure lower than 4 atmospheres.

Response to amendments and arguments.

Applicant's amendments and arguments have been considered and they are persuasive. Therefore, rejection of 1-8, 10-13 and 15 under 35 U.S.C. 102(b) is hereby **withdrawn**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

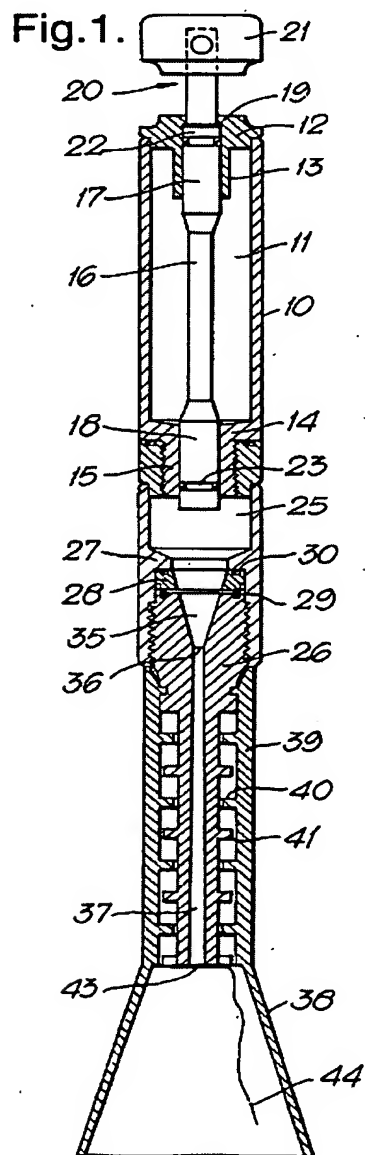
Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellhouse et al. (WO 94/24263, of record, hereinafter Bellhouse) in view of Bhat et al. (J. Appl. Genet. 2001, 42(4): 405-412, hereinafter Bhat).

This is a new ground of rejection necessitated by Applicant's amendments to the claims.

Bellhouse teaches a needle-less syringe using supersonic gas flow for particle delivery comprising a gas chamber, the gas of which is discharged by way of an actuating pin (meeting the limitation to the controller valve of the instant inventions wherein a valve is understood by a person of skill in the art to mean a device that controls the movement of liquids or gases through pipes or other passages by opening or closing ports and channels) into a rupture chamber (equivalent to the instant claims pressurized chamber) until the gas establishes pressure wherein the chamber contains a membrane comprising at least the biological material to be delivered (meeting the limitation of triggering the gun and providing gas through the controller valve to the pressurized chamber until the gas establishes pressure). The sample solution comprising at least the biological material is released from the material delivery system when the membrane ruptures and is accelerated by the gas in the

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pressurized chamber. The sprayer, illustrated in Figures 1 of Bellhouse includes a converging/diverging spray nozzle (the lower hatched area between the segments labeled 35 and 37) and diverging straight discharge tube (the bottom element of the sprayer labeled 38). The device of Bellhouse therefore contains all of the structural elements of the gene gun device of claims 1, 11 and dependent claims.



Bellhouse teaches that the material to be delivered may be biological including genetic material, p. 2, ¶2, meeting the limitation of nucleic acid (claim 2), insulin and calcitonin, (protein of claim 3), viruses or protein for immunization (claims 4-6) p. 3, ll. 20-24 or material for genetic therapy, p. 2, l. 9 (claim 15). Particle velocity may be between 200-2,500m/sec, p. 4, l. 30 (claim 7). The gas employed in using the device may be helium, p. 7, l. 13 (claim 10). The angle between the diverging part and the center axis of the Bellhouse spray tube is also less than 15 degrees, see Fig. 1 above between the sections marked 36 and 43 (claims 9 and 14). Further, the interior contour of the converging part of the spray neck at the section labeled 36 appears to meet the limitation of claims 9 and 14 defined by the range $r_t < R_t < 2r_t$ where R_t is the curvature radius of the converging part and r_t the radius of the spray neck. Also, as the reference device is similar in design to the instant claimed inventions, presumably a pressure at the sprayers outlet of about 1 atmosphere may be achieved (claim 8). The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2 d 1922, 1923 (BPAI 1989).

Bellhouse does not explicitly teach a pressurized chamber comprising a gas pressure lower than 4 atm.

Bhat teaches particle inflow gun mediated transformation of buffel grass and parameters for optimizing the genetic transformation including helium pressure of 2, 4, 5 and 6 bars (see especially the Abstract and p. 408, Table 1), wherein a bar is recognized by the skilled artisan to represent 0.098692 atmosphere (atm), meeting the limitations of claims 1 and 11. Further, the plasmid DNA was suspended in a solution of sterile water (see especially p. 407, ¶2), meeting the instant limitation of a sample solution.

A person of skill in the art would have been motivated to modify Bellhouse device to use a pressure of less than 4 atm with a bombardment sample in solution in order to enhance operation of the device, for transfection of cells for example. Motivation comes directly from Bhat, who found that the pressure of 4 bars was found to be the best assayed for expression of their plasmid DNA in solution (see especially p. 408, ¶2 and the Abstract). Given the level of skill in the art of the time of the instant invention, the skilled artisan would have had every expectation of success in combining the teachings of Bellhouse and Bhat to construct the instant claimed inventions.

Response to arguments

Applicant has provided arguments with respect to the previous rejections under 35 USC § 102, which have been withdrawn, but which arguments are relevant to the present rejection 35 USC § 103.

Applicant argues that Bellhouse teaches a delivery system used for particle delivery, and that this does not comprise sample solution delivery. The Office disagrees. A "solution" may be interpreted by a person of ordinary skill in the art to comprise "a homogeneous mixture of two or more substances, which may be solids (emphasis added), liquids, gases, or a combination of these" (The American Heritage® Dictionary of the English Language: Fourth Edition. 2000, <http://www.bartleby.com/61/33/S0553300.html>). Thus, the skilled artisan would interpret the particles described by Bellhouse as fully meeting the limitations of a "sample solution" of all instant claims.

Applicant also argues that Bellhouse does not teach the limitation of claims 9 and 14 that the angle between the diverging part and the center of axis of the spray tube is 15 degrees, because the "drawing is just a diagram and not a real structural drawing. Further applicant argues that the instant limitation " $r_t < R_t < 2r_t$ wherein R_t represents the curvature radius of the converging part and r_t the radius of the spray neck". Applicant's arguments are not persuasive. First, the Office notes that the diagrams provided by Bellhouse are similar to those in the instant disclosure (Figs. 1 and 2, for example). Second, as noted above, the interior contour of the converging part of the spray neck at the section labeled 36 appears to meet the limitation of claims 9 and 14 defined by the range $r_t < R_t < 2r_t$ where R_t is the curvature radius of the converging part and r_t the radius of the spray neck. Further, the Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional

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characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2 d 1922, 1923 (BPAI 1989).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Guy Guidry, Ph.D. whose telephone number is 571-272-7928. The examiner can normally be reached on Monday through Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution

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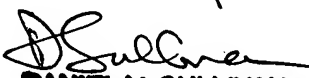
of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Guy Guidry, Ph.D.

Examiner

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DANIEL M. SULLIVAN
PATENT EXAMINER